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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/760,197	01/12/2001	Pedro Aloise	BIO76701	2671

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EXAMINER

SAYALA, CHHAYA D

ART UNIT	PAPER NUMBER
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1761

DATE MAILED: 09/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/760,197	ALOISE ET AL.	
	Examiner	Art Unit	
	C. SAYALA	1761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) Paper No(s). <u>20030828</u> . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/28/03 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 1-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The new limitation "used as a media and having a substantially neutral pH" could not be found in the specification as originally filed. If applicant can point out where such terminology occurs in the specification, as originally filed, this rejection will be withdrawn.

The specification does not provide sufficient evidence to persons skilled in the art that the specification as filed contemplated the above limitations now claimed. See MPEP 2163. The standard for evaluating new matter in the claims is not whether the subject matter would be obvious to one skilled in the art from the specification as originally filed. An objective standard for determining compliance with the written description requirement is, "does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed." *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989). Under *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991), to satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, and that the invention, in that context, is whatever is now claimed. The test for sufficiency of support in a parent application is whether the disclosure of the application relied upon "reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter." *Ralston Purina Co. v. Far-Mar-Co., Inc.*, 772 F.2d 1570, 1575, 227 USPQ 177, 179 (Fed. Cir. 1985) (quoting *In re Kaslow*, 707 F.2d 1366, 1375, 217 USPQ 1089, 1096 (Fed. Cir. 1983)). See MPEP 2163.02.

Claim Rejections - 35 USC § 102/35 USC § 103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 98/34498 and Stone et.al. (J. Sci. Food Agric. Vol 35, pp 513-519, 1984) in view of EP 0321004 and Nielsen et al. (US Patent 5989600).

'498 teaches mixing krill hydrolysate with soy, canola and other plant protein along with wheat bran, being brought to a desired temperature of about 45⁰ C, and holding it for about 1 hour at this temperature. At page 19, lines 9+, the reference states that the enzymes in krill carry out a *limited hydrolysis* of soy, canola and other plant proteins. The phytic acid and levels of acid and base are measured. Wheat bran is used to provide phytase. The patent teaches that the blend can be maintained to an extended period of time, 4 hours or even longer. The krill hydrolysate product is evaporated and then mixed with and co-dried with a dry carrier, such as canola meal, oil seed meal, which renders obvious the soybean meal and other vegetable meals. The advantages are given at p. 20; see page 19 and page 22, lines 5-10.

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'498 also teaches using formic acid to stabilize the hydrolyzed marine protein. It does not teach adding acid to stabilize hydrolyzed feed materials from vegetable/oil seed protein. However, it would have been obvious to use the same acid to stabilize such since the krill hydrolysate used is the same.

The patent does not teach the use of a phytase enzyme instead of wheat bran, and does not teach the use of a pH between 5-5.5.

Stone et. al teach acid-stabilized blend of fish silage, wheat bran and canola meal to make a feed-stuff. The pH is maintained at 4.0 and the final blend is dried. Stone et al. teach stabilizing the product with acid at page 518, second paragraph. The use of phytase enzyme is not taught and neither is the pH the same as claimed herein.

EP 0321004 teaches the uses of phytase *either* from wheat or from microbial source. It also teaches using a combination of enzymes that possess plant degrading properties. See claims 1-4. See claim 6, wherein the process teaches drying the hydrolyzed product.

Nielsen et al. also teach using a combination of enzymes such as phytase and proteolytic enzymes for dephosphorylating the same cereals as claimed herein and shown by '498, see col. 1, lines 53-55; col. 3, lines 40-65. The pH used is between 4-7. The temperatures are from 35-65°C. See col. 3, lines 10-25.

It would have been obvious to combine krill hydrolyzate, canola meal, phytase or other film-degrading enzymes used in EP '004 or Nielsen et. al., to prepare a feedstuff as taught by WO '498 and drying the hydrolyzed product as shown in the secondary

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reference and co-drying with other feed ingredients as shown by '498. Note that all patents are drawn to hydrolyzing feed materials to make animal feedstuff by using phytase enzyme. To substitute the wheat bran of the primary references (Stone et.al, WO '498) with phytase would have been an obvious substitution since these references teach that wheat bran is used as a phytase source and both Nielsen et. al. and EP '004 use the phytase enzyme itself. The temperatures shown by these references are close to or encompass these parameters claimed herein and to optimize such, based on the known phytase activity around pH 5 to 5.5 would have been an obvious expedient. It is well known that each enzyme has optimal activity at a specific temperature and pH, as also phytase. And therefore, it is immaterial if the krill hydrolysate is a neutral media or not, because it would have been obvious to one of ordinary skill in the art at the time to adjust such conditions anyway, to what would be optimal for phytase activity.

3. Claim 15 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over WO98/34498, or Stone et.al., or EP 0286056, or Vanderbeke et. al. (US Patent 5554399) or Nielsen et. al (US Patent 5989600) or WO 00/10404 or EP 0321004.

The patents/references above teach the addition of enzymes such as phytase to hydrolyze the same feed materials as claimed herein. The flavors are in amounts 0-5% (see claim 1). The rejection is being made under both statutes because the Office is not equipped to make prior art products and compare them with those of applicant's claims

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and so the burden is being shifted to applicant to show that these product claims are distinguishable over prior art. Applicants' claim is written in product-by-process format and as such, it is the novelty of the instantly claimed product that need be established and not that of the recited process steps. In re Brown, 173 USPQ 685 (CCPA 1972); In re Wertheim, 191 USPQ (CCPA 1976). When the prior art discloses a product that reasonably appears to be either identical with or only slightly different than the product claimed in this product-by-process claim, the burden is on the applicant to present evidence from which the Examiner could reasonably conclude that the claimed product differs in kind from those of prior art. In re Brown, 459 F2d 531, 173 USPQ 685 (CCPA 1972); In re Fessman, 489 F2d 742, 180 USPQ 323 and 324 (CCPA 1974); In re Marosi, 710 F2d 799, 218 USPQ 195 (Fed Cir. 1983).

Response to Arguments

4. Applicant's arguments filed 7/28/03 have been fully considered but they are not persuasive.

Applicant has argued that WO 98/34498 does not teach the addition of phytase exogeneously, but does show endogeneous addition by using wheat bran. First, this rejection is made under 35 USC 103, not 35 USC 102. Second, the patent teaches phytase enzyme in the form of wheat bran for it was known in the art at the time the invention was made that wheat bran was used for its phytase activity. See Stone et al. that uses fish silage (instead of krill hydrolysate) and canola meal with wheat bran, expressly stating that the canola meal was dephosphorylated by phytase from the

wheat bran (see abstract). This reference was used to show that in a similar process, wherein fish silage, enzymatic wheat bran and cereal are blended and dried, acid is used to stabilize the product. Applicant's criticism that Stone et al teach fish silage instead of fish hydrolysate or that the purpose of adding an acid to the product is different from the purpose intended in the instant invention is not convincing. As stated before, Stone et al. add acid to stabilize the product and it for this reason that the reference was used with the reasonable expectation that it would stabilize the fish hydrolyzate product as well. "Assertion that examiner combines prior art references for purpose different from that envisioned by inventors does not warrant reversal of examiner's finding of obviousness". *Ex parte Raychem Corp*, 17 USPQ2d 1417.

Apart from the above patents/reference, Nielsen et al teach at col. 1, lines 53-55, col. 3, lines 40-65 that phytases are obtained from microorganisms as well as wheat bran, that they dephosphorylate cereals, and that the process is carried out at pH=4-7 and temperatures of 35-65⁰C. It is for this teaching alone that this reference was applied and this teaching was considered important. Applicant's discussion of Nielsen et al. is therefore, irrelevant because it addresses other limitations for which the reference was not used.

Furthermore, EP 0321004 teaches the equivalence of phytase enzyme produced microbially and phytase produced by wheat bran. See page 3, lines 5-20. EP '004 teaches the temperature when the enzyme is applied to the cereal: 20-60⁰C and teaches that the phytase is active at the low pH of 4-5. At page 3, lines 45-50, enzyme dosages, and a phytin degrading unit definition is also given. See "standard conditions"

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for phytase given as 40⁰C and pH=5.5 and it is well known that each enzyme has its specific temperature and pH for optimum activity. Applicant's argument that the reference is inapplicable because the reference teaches sulfur dioxide as a preservative is irrelevant because it is not for its teaching of a preservative but for its showing of equivalency for microbial phytase and wheat bran phytase that the reference was applied.

Finally, WO 98/34498 teaches wet krill hydrolysate mixed with dry carrier in the form of vegetable protein shown on page 19, lines 1-7 as canola, corn, soy, etc. Note the cereals shown in Nielsen et al, also the same. WO'498 teaches using wheat bran, which inherently contains phytase, and teaches that formic acid stabilizes hydrolyzed marine protein. See pages 30-32. Stone et al. teach stabilizing their fish silage and canola meal mixture that has been hydrolyzed with acid. See page 518, second paragraph. Thus, not only would it have been obvious to substitute wheat bran used for its phytase, with phytase from microorganisms (EP '004) but also to stabilize with acid as Stone et al has done as also WO '498. One of ordinary skill in the art is held accountable not only for the specific teachings of references, but also for the inferences which those skilled in the art may reasonably be expected to draw. In re Hoeschele, 160 USPQ 809, 811, (CCPA 1969).

Applicant's response to the rejection and his citing the decision of In re Mills has been carefully considered but is deemed to be unconvincing. In response, In re Hoeschele indicates that "the inferences which those skilled in the art may reasonably be expected to draw" must also be considered. Also, see Ashland Oil Inc. v. Delta

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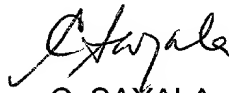
Resins and Refractories, Inc. et al. 227 USPQ 657 (CAFC 1985) wherein it was stated that "To properly combine two references to reach a conclusion of obviousness, there must be some teaching, suggestion or inference in either or both of the references, or knowledge generally available to one of ordinary skill in the art, which would have led one to combine the relevant teachings of the two references."

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. SAYALA at Group 1761, telephone number (703) 308-3035.

The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3599.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is 703-308-0661.


C. SAYALA
Primary Examiner
Group 1700.